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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/04/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,850

Applicant(s)

UENO ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 6-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/509,778.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/1/03 has been entered.

After further review and consideration this application is not in a condition for allowance at this stage for following reasons.

1. Rejections withdrawn:

1,1, The amendment together with remarks and arguments, presented in paper # 7 dated 9/22/03 have been considered favorably and found persuasive. Rejections under 35 U.S.C. 112 paragraph second are now withdrawn.

1.2. The amendment presented in paper # 7 dated 9/22/03 have been considered favorably and found persuasive. The Rejections made under 35 U.S.C. 102(b) over Behrens (U.S.P.' 163), Lerch et al (DE 2314985), and Chao et al are now withdrawn because applicants' provisos delete the instant compounds which overlap the references'.

2. Rejections maintained:

Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Simmonds et al (G.B. 1545767) teaches structural isomers. Applicants only presented arguments: " The instant compounds have serotonin receptor muscle relaxant activity". This is not sufficient. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2141.02 and MPEP § 2112.01.

3. New Rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3.1. Claims 1,4,9,10,17 are rejected under 35 U.S.C. 102(b) as being anticipated by over E.Gy.T. et al(NL 8002119, also cited as Chemical Abstracts DN 94:174912).

The ref. '119 teaches the derivatives of 3-amino-isoquinoline having utility as spontaneous motility-inhibitors.

The compound having CAS RN # 77454-38-7 (Isoquinoline, 1,3-di-morpholinyl- is encompassed by the instant claims wherein R1 = H; R3 =H; N = zero; B = optionally substituted heteroaryl; R2 = 4-morpholinyl group. .

3.2. Claims 1,4,9,10,17 are rejected under 35 U.S.C. 102(b) as being anticipated by Th. Karl (FR. 2268524, also cited as Chemical Abstract DN 85: 160167). See compounds with CAS RN # 60691-09-0 (isoquinoline, 3-(4-methyl-1-(4-morpholinyl)- . The instant claims read on the ref.' 524 compounds with instant R2 = 4-morpholinyl; R3 = H; n = zero; B = Optionally substituted heteroaryl. See pages 47,49,50 of the Chemical abstracts for formulae of the compounds.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4.1. Claims 1,4,6-10,12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aebi et al(CH 4328308, also cited as Chemical Abstracts DN 69:35972).

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The ref. '308 teaches the derivatives of 1 alkyl-3-amino-isoquinoline having utility as cough suppressing pharmaceuticals. See column 3 lines 1-6.

The ref. compounds differ from the instant claims by having instant R3 = -CH₂-H instead of H only. See compounds of Examples 1, 2, 3, 4,5,6 in columns 5-7.

Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to prepare instant compounds by modifying or replacing as:

(I). Replacing 4-position -CH₃ by H i.e. unsubstituted core of isoquinoline, and try out the use/utility as a pharmaceutical by using the conventional chemistry knowledge. The motivation stems from the expectation of making compounds having equal or better medicinal agent.

4.2. Claims 1,4,6-10,12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nair et al (Indian J. Chem. 10/4,337-40(1972), also cited as Chemical Abstract DN 77:164414 copy is enclosed).

The ref. Nair teaches the derivatives of 1 alkyl-3-amino-isoquinoline having 4-alkyl-1-piperazineethanol, 4-[[1-[4-(2-hydroxyethyl)-1-piperazinyl-methylene. See compound with CAS RN # 14576-16-0.

Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to prepare instant compounds by modifying or replacing as:

(I). Replacing 4-position -CH₃ by H i.e. unsubstituted core of isoquinoline, modifying the H of OH of 2-Hydroxyethyl by alkyl, and try out the use/utility as a pharmaceutical by using the conventional chemistry knowledge. The motivation stems from the expectation of making compounds having equal or better medicinal agent.

Analogous alkyl variations would be structurally obvious. See, In re Dillon, 919 F. 2d at 1904. See also Deuel, 51 F. 3d at 1558, 34 U.S.P.Q. 2d at 1214 ("Structural relationships may provide the requisite motivation or suggestion to modify one compound to obtain another compound(s)"). For example, one compound may suggest its homolog/isomer, because homolog/ isomer often have similar properties, and therefore, chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties, or merely to satisfy their production goals.

Claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F. 2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2141.02.

1. Claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Simmonds et al (G.B. 1545767) teaches structural isomers. Applicants only presented arguments: " The instant compounds have serotonin receptor muscle relaxant activity". This is not sufficient. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2141.02 and MPEP § 2112.01.

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It has been held that a prior art disclosed compounds is sufficient to render a prima facie case of obviousness as species falling within a genus. See *In re SUSI*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by Federal Circuit in *Merck & co. V. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir.1989). See *In re Dillon* 16 USPQ 2d. 1897, 1923 regarding a prima facie case of obviousness of structurally similar compounds disclosed by prior art" regardless to the properties disclosed in the inventor's application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,4,6,7-9,11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply.

(A). Claims 1,4,6,7-9 recite: " A condensed pyridine compound represented by following formula.". Correction to: " A compound represented by following formula," is required.

(B). Claim 1 recite B component as: " optionally substituted ary, optionally substituted heteroaryl.". This is indefinite because the claim does not represent exactly the structure and core, exact point(s) of attachment to the carbon atoms with respect to rings they represent. Correction is required.

(C). Claim 8 recites : " A pharmaceutical composition for treating or ameliorating disease against which serotonin antagonist is efficacious". It is not very clear as to what applicants want to present with efficacious.

(D). Claim 11 also recite: " efficacious". It is not very clear as to what applicants want present with.

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(D). Claims 8,9, recite pharmaceutical composition using a compound or its pharmaceutically acceptable salt or hydrate. Usually a pharmaceutically acceptable carrier is also mixed with the compounds for making a composition. Correction is required.

Claims 12,13-17 are rejected because they are dependent on rejected claims.

Claim Rejections - 35 USC § 101

6. Claim 10 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a process or step asserted utility or a well established utility.

The claims do not exactly recite which pharmaceutical composition of compound(s), pharmaceutically acceptable salts thereof. Is it claim 7 or claims 8-9 composition(s)?

Claim 10 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a step or process of making the process or step of using asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claim 6 has 427 compounds. This number of compounds cannot be considered "a reasonable number" according to rule 1.140(a). See also MPEP rule 1.141(a).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc. Tech., whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM.

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If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

Mukund J. Shah
MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 1600

Sp/-

July 28, 2003.